PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY PCT To: WRITTEN OPINION OF THE see form PCT/ISA/220 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1) Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet) Applicant's or agent's file reference FOR FURTHER ACTION see form PCT/ISA/220 See paragraph 2 below International filing date (day/month/year) International application No. Priority date (day/month/year) 27.02.2004 PCT/IB2005/000479 23.02.2005 International Patent Classification (IPC) or both national classification and IPC A61J3/07 **Applicant** I.M.A. INDUSTRIA MACCHINE AUTOMATICHE S.P.A. This opinion contains indications relating to the following items: 1. Basis of the opinion ☑ Box No. I ☐ Box No. II **Priority** Non-establishment of opinion with regard to novelty, inventive step and industrial applicability ☐ Box No. III ☐ Box No. IV. Lack of unity of invention Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement ☐ Box No. VI Certain documents cited Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application **FURTHER ACTION** 2. If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notifed the International Bureau under Rule 66.1 bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. For further details, see notes to Form PCT/ISA/220. 3.

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/IB2005/000479

Box No. I Basis of the opinion
1. With regard to the language , this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
a. type of material:
□ a sequence listing
☐ table(s) related to the sequence listing
b. format of material:
☐ in written format
☐ in computer readable form
c. time of filing/furnishing:
contained in the international application as filed.
filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/IB2005/000479

AP20 Rec'd PCT/PTO 21

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or Box No. V industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims

6-8,10-16,20-25

No:

Claims

1-5,9,17-19

Inventive step (IS)

Yes: Claims

No:

Claims

1-25

Industrial applicability (IA)

No:

Yes: Claims

Claims

1-25

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

- 1 Reference is made to the following documents:
 - D1: GB-A-2 025 270 (CAPSUGEL AG) 23 January 1980 (1980-01-23)
 - D2: WO 95/34269 A (WARNER-LAMBERT COMPANY) 21 December 1995 (1995-12-21)
 - D3: US-A-4 466 844 (MACLAUGHLIN ET AL) 21 August 1984 (1984-08-21)
 - D4: EP-A-0 110 603 (WARNER-LAMBERT COMPANY) 13 June 1984 (1984-06-13)
 - D5: US-A-4 656 066 (WITTWER ET AL) 7 April 1987 (1987-04-07)
- 2 The present application does not meet the criteria of Article 33(1) PCT,
- 2.1 The document D1 (page 2, line 117 page line 7, fig. 1 3) discloses (the references in parentheses applying to this document):

A capsule filling machine for the production of sealed capsules of the type with lid (C) and body containing pharmaceutical material, the machine being of the type comprising a station (19) for feeding the capsule bodies and lids (C); a dosing station for filling a dose of the material into each capsule body; and a station (22) for closing the capsules by placing each lid (C) over the respective body so that their respective annular ends overlap, whereby between the dosing station and the closing station (22) there is at least one intermediate operating station (21) for applying a sealing substance in the vicinity of the ends.

Therefore, the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

2.2 Document D1 also discloses a method including all the steps of claim 17. The same applies for documents D2 (page 11 - page 10, line 12, fig. 1 - 6) and D3 (column 2 - column 3, line 4, fig. 1 - 4). Therefore, the subject-matter of claim 17 is also not new in the sense of Article 33(2) PCT.

2.3 Dependent claims 1 to 16 and 18 to 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

Novelty:

D1, page 2, line 117 - page line 7, fig. 1 - 3; for claims 2 - 5, 9, 19
D2, page 11 - page 10, line 12, page 13, lines 14 - 28, fig. 1 - 6; for claim 18
D3, column 2 - column 3, line 4, fig. 1 - 4; for claim 18

Inventive step:

D2, page 13, lines 14 - 28, fig. 3; for claim 10
D4, page 2, lines 22 - 36, page 3, lines 19 - 24, page 5, lines 13, 14, fig. 1, 2; for claims 7, 8, 14 - 16, 20 - 24
D5, column 9, line 56 - column 10, line 25; fig. 4, 5; for claims 12, 13 and 25

The use of vacuum holders is common practice in the field (e.g. D2, page 1, lines 14 - 28). D4 (page 4, lines 7 - 23, fig 2) discloses an apparatus comprising means for holding capsules and a jet to direct a stream of sealing substance onto a rotating capsule. Consequently, claim 6 does not involve an inventive step.

The same vacuum holder, including rotation and vertical displacement, could be use to bring lid and body of the capsule together. This feature is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to close the capsule and spread the sealing substance over the surfaces of the two ends. Hence, no inventive step is present in the subject-matter of claim 11.

Remarks:

When entering the European Regional Phase the applicant should have in mind that the EPO cannot grant two patents to the same applicant for one invention. This application PCT/IB2005/000479 and application PCT/IB2005/00487, also from the same applicant, include some claims claiming the same subject-matter.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (SEPARATE SHEET)

International application No.

PCT/IB2005/000479

Re Item VII

Certain defects in the international application

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.